

Biocompatibility & Safety – ISO 10993

Qserve offers” Biocompatibility & Safety – ISO 10993 and FDA” expert services, to assist medical device manufacturers to access the medical device market. Qserve has considerable in-house expertise in the biocompatibility and safety of medical devices.

Submissions for approval of medical devices by regulatory authorities require that biocompatibility assessment be conducted to assure the safety of the device or materials incorporated in the device. These assessments follow the ISO 10993 “Biological Evaluation of Medical Devices” series and the FDA guidance document, Blue Book Memorandum #G951 relating to this series. A material is considered to be biologically safe when its performance and application benefits outweigh any biological safety risks associated with its use on or in the human body. Risk analysis is therefore crucial to determining biological safety.

The interaction between a biomaterial and its host environment (cells, tissues and tissue fluids) is dynamic and complex. Cells, through the action of body elements such as proteins, antibodies, or phagocytes can have an affect on the biomaterial, resulting in its degradation. In turn this can produce wear products and leached substances that can affect the host tissue. Responses may be localized or systemic.

Your company can, with confidence, entrust the identification of the test work required to our highly experienced industry professionals. Moreover, Qserve has close relationships with the major test houses worldwide. Our in-depth knowledge of global regulatory requirements means that testing can be recommended which will meet multiple regulatory requirements, saving you time and money.

Qserve offers a full range of services including:

- GAP Analysis (a first assessment to verify what is needed)
- Search and review of all the available biological safety data concerning similar materials and products in the public/scientific literature
- Review of the suitability of available test data
- Identification of biological safety hazards and potential harms - Risk Analysis
- Design of test strategies
- Selection of a biocompatibility safety test house
- Project management
- Overall biological safety evaluation rational/report based on the outcomes that is suitable for certification purposes worldwide
- Training in biological safety evaluation
- Experienced Consultants, who work closely with you, to ensure timely and on budget implementation of the project/studies

If you would like more information or a free consultation and price quotation, please contact us.